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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,054	12/16/2004	Chang-Ming Yang	YANG52	3511

23123 7590 03/29/2010

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SUITE # 101
MESA, AZ 85201

EXAMINER	
SYED, ATIA K	

ART UNIT	PAPER NUMBER
3769	

MAIL DATE	DELIVERY MODE
03/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,054	YANG, CHANG-MING	
	Examiner	Art Unit	
	ATIA SYED	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *18 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 8-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges the amendment filed on June 18, 2009.

Response to Arguments

Applicant's arguments filed June 18, 2009 are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 12-18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shusterman US Patent Publication Number 2003/0023146 in view of Kloecker US Patent Number 6,315,745 and Heilman et al. US Patent Publication Number 2003/0158593 (hereinafter Heilman).

In regards to claim 1, Shusterman discloses a method of monitoring the physiological functioning and conditions of a person comprising:

the step of using sensors in a garment body comprised of a jacket having a torso portion (Shusterman; fig 6 disclose a jacket having a torso portion, [84]) worn by the person to continuously monitor the physiological functioning and conditions of the person (figs 2A and 2b,

the jacket of fig 6 monitors patients physical condition via sensor 218 and blood pressure cuff; Shusterman, [0006, 0044 and 84 and 92]), and

the step of using a monitoring center unit (patient monitoring unit 214) to transmit monitored data to a proximity or remote control center (central station 100) through a communication port (PC 202 of the patient remote cite has a port to communicate with the central station; fig 2B and [0046-0050] and common port 208a [0050])so that the user can interact with the monitoring center unit (Shusterman [0006, 0041, 0044]) or the user can have a two-way interaction with the remote control center, thereby providing related information to medical care persons at the remote side for diagnosis or giving an instruction to a person at the proximity side to take emergency measures.

Shusterman also teaches the step of providing drug therapy to the patient (a medication dispensing device, fig 2A, unit 212). However, Shusterman does not disclose the step of using at least two different types of medical treating devices mounted in predetermined zones of the garment body for applying medical treatments to the user wearing the garment body.

Kloecker, a reference in an analogous art, discloses a garment comprising air bags for treating lymphedema and other related illnesses (abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the garment disclosed by Shusterman in view of garment taught by Kloecker since doing so would provide a treating device for lymphedema in addition to the drug therapy taught by Shusterman.

Shusterman modified by Kloecker disclose one type of medical treatment device in form of the airbags and also discloses ECG sensors to monitor a patient's cardiac activity (Shusterman

[0092]). Shusterman modified by Kloecker fail to disclose a second medical treatment device of a different type mounted in predetermined zones of the garment body for applying medical treatments to the user wearing the garment body.

However Heilman, a reference in an analogous art discloses a cardiac garment with a wearable defibrillator (an electroshock device therefore equivalent to another medical treatment device mounted in predetermined zones of a garment body) that applies electric therapy to heart muscle if an arrhythmia is detected using ECG sensors (Heilman abstract and [0002 and 0010]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the method of Shusterman and Kloecker that uses ECG sensors to monitor a patient's cardiac activity with Heilman's step of providing a wearable external defibrillator that uses the ECG data to apply electric therapy if an arrhythmia is detected because this permits the application of electric treatment to the heart muscle quickly and Heilman discloses that time delays in applying the corrective electrical treatment may result in death and the treatment is needed within a few minutes to be effective (Heilman [0005-0006]).

Claim 2 is rejected on substantially the same bases, see previous office action for details of rejection.

In regards to claim 12, Shusterman discloses an apparatus for monitoring the physiological functioning and conditions of a user, comprising:

a garment body comprised of a jacket having a torso portion and wearable to a user (Shusterman Figure 6 disclose a jacket having a torso portion, [84]);

first and second sensors mounted in the garment body for detecting the physiological functioning data and conditions of the user wearing the garment body (Shusterman, Figure 6, the jacket monitors patients physical condition via sensor 218 and blood pressure cuff; [0006, 0044 and 0083-0088]);

a communication port (PC 202 of the patient remote cite has a port to communicate with the central station; fig 2B and [0046-0050] and common port 208a [0050]) for transmitting the physiological functioning data and conditions to a remote control center on the real time or at a delayed time or receiving and answering the inquiries of the user (Shusterman [0041, 0044]);

a monitoring center unit electrically connected with the sensors and the communication port for receiving and transmitting signals such that the communication port is used to transmitting the monitored data to the remote control center, the monitoring center having I/0 ports connectable to the sensors and medical devices (Shusterman [0006, 0041, 0044, 0089], also see fig 2A and 2b for serial port 208);

whereby the monitoring data of the user's physiological functioning and conditions is stored, managed and analyzed to find out abnormal conditions of the user for further treatments (Shusterman [0006, 0054]).

Shusterman also teaches a device for providing drug therapy to the patient (a medication dispensing device, fig 2A, unit 212). However, Shusterman does not disclose first and second medical treating devices mounted in the garment body for applying medical treatments to the user wearing the garment body, wherein the first and second medical treating devices are of different types of medical treating devices, spaced apart from each other and connected to the

first and second sensors, respectively, the medical treating devices electrically connected to the monitoring center unit or communication port.

Kloecker, a reference in an analogous art, discloses a garment comprising air bags for treating lymphedema and other related illnesses (column 9, line 52 – column 10, line 56). The inflatable bags further having pressure sensors 9 (inflatable elements are airbags thus the different airbags are equivalent to a first type of medical treatment devices mounted in predetermined zones of a garment body, spaced apart and connected to first sensors; column 10, lines 35-56).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the garment disclosed by Shusterman in view of garment taught by Kloecker since doing so would provide a treating device for lymphedema in addition to the drug therapy taught by Shusterman.

Shusterman modified by Kloecker disclose one type of medical treatment device in form of the airbags and also discloses ECG sensors to monitor a patient's cardiac activity (Shusterman [0092]). Shusterman modified by Kloecker fail to disclose a second medical treatment device of a different type mounted in predetermined zones of the garment body and connected to a second sensor.

However Heilman, a reference in an analogous art discloses a cardiac garment with a wearable defibrillator (an electroshock device therefore equivalent to another medical treatment device connected to second sensors mounted in predetermined zones of a garment body) that applies electric therapy to heart muscle if an arrhythmia is detected using ECG sensors (Heilman abstract and [0002 and 0010]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Shusterman and Kloecker that uses ECG sensors to monitor a patient's cardiac activity with Heilman's feature of providing a wearable external defibrillator that uses the ECG data to apply electric therapy if an arrhythmia is detected because this permits the application of electric treatment to the heart muscle quickly and Heilman discloses that time delays in applying the corrective electrical treatment may result in death and the treatment is needed within a few minutes to be effective (Heilman [0005-0006]).

13. The apparatus as claimed in claim 12, wherein the garment body, first and second sensors and first and second medical treating devices are wearable by the user and removable from the user as a single unit (Shusterman figure 6, Kloecker figure 2 and Heilman figures 1a-b. It is the Examiner's position that the apparatus resulting from the combination of the three references would be capable of being worn and removed as a single unit).

Claims 14-17 are rejected on substantially the same basis as independent claim 12.

18. The apparatus as claimed in claim 12, wherein the first and second sensors are selected from the group consisting of *pressure sensors*, temperature sensors, terminal sensors, voice sensors, *biochemical sensors* and biochips (Shusterman, Figure 6 [0083-0088], Kloecker column 10, lines 35-56 and Heilman Abstract).

Claim 21 is rejected on substantially the same bases as claim 1 and 12. Applicant is advised that further limiting the structure of a jacket or sensors within the jacket does not add any manipulative steps to the claimed method.

Claims 3-5 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shusterman in view of Heilman et al. US Patent Publication Number 2003/0158593 (hereinafter Heilman).

In regards to claim 3, Shusterman discloses apparatus for monitoring the physiological functioning and conditions of a user, comprising:

a garment body comprised of a jacket having a torso portion and wearable to a user, the garment body having a plurality of zones (Shusterman Figure 6 disclose a jacket having a torso portion, [84]);

sensors mounted in the zones of the garment body respectively for detecting the physiological functioning and conditions of the user wearing the garment body (Shusterman Figure 6, [0007]);

a communication port for transmitting the monitored data to a remote control center on the real time or at a delayed time or receiving and answering the inquiries of the user ((PC 202 of the patient remote cite has a port to communicate with the central station; fig 2B and [0046-0050] and common port 208a [0041, 0044, 0050]);

a monitoring center unit electrically connected with the sensors and the communication port for receiving and transmitting signals such that the communication port is used to

transmitting the monitored data to the remote control center, the monitoring center having I/O ports connectable to the sensors (Shusterman [0006, 0041, 0044, 0089]);

whereby the monitoring data of the user's physiological functioning and conditions is stored, managed and analyzed to find out abnormal conditions of the user for further treatments (Shusterman [0006, 0054]).

Shusterman also teaches a device for providing drug therapy to the patient (a medication dispensing device, fig 2A, unit 212). Shusterman further discloses ECG sensors to monitor a patient's cardiac activity (Shusterman [0092]). However, Shusterman does not disclose a medical treating devices connected to the monitoring center unit or communication port and mounted in predetermined zones of the garment body for applying medical treatments to the user wearing the garment body, wherein the medical treating devices are selected from the group consisting of oxygen source devices, pumps, air bags, body temperature regulators, pain-causing devices, hypodermic syringes and electroshock devices, wherein the air bags are of the type to correct the posture of the user, to fix a broken bone in position, to stop bleeding of blood, to apply cardio-pulmonary resuscitation or abdominal thrust (Heimlich maneuver) to the user.

However Heilman, a reference in an analogous art discloses a cardiac garment with a wearable defibrillator (an electroshock device mounted in predetermined zones of a garment body i.e. Shusterman has a jacket with predetermined zones, modifying Heimlich with Shusterman would eliminate the need of straps for holding the electroshock device since it can be mounted on the jacket) that applies electric therapy to heart muscle if an arrhythmia is detected using ECG sensors (Heilman; abstract and [0002 and 0010]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the drug therapy of Shusterman that uses ECG sensors to monitor a patient's cardiac activity with Heilman's feature of providing a wearable external defibrillator that uses the ECG data to apply electric therapy if an arrhythmia is detected because this permits the application of electric treatment to the heart muscle quickly and Heilman discloses that time delays in applying the corrective electrical treatment may result in death and the treatment is needed within a few minutes to be effective (Heilman [0005-0006]).

Claims 4 and 5 are rejected on substantially the same bases, see previous office action for details on rejection.

Claim 8 only further limits the airbags of the Markush group. The rejection of claim 3 also rejects claim 8, since claim 3 was rejected based on another member of the Markush group i.e. electroshock device.

Claims 9-11 are rejected on substantially the same bases, see previous office action for details on rejection.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shusterman, Kloecker and Heilman as applied to claim 1 above and further in view of Starkweather et al. US Patent Publication Number 2001/0041920 (hereinafter Starkweather).

Shusterman as modified by Kloecker and Heilman disclose that one of the biosensors is a glucose sensor (Shusterman [0092]). Shusterman, Kloecker and Heilman do not disclose that the sensor is implanted in the user.

However Starkweather, a reference in an analogous art discloses that an external glucose sensor and an implanted glucose sensor are substitutable as means for determining glucose levels (Starkweather [0051]).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Shusterman by substituting the external glucose sensor with Starkweather's implanted glucose sensor because Starkweather discloses that implanted and external sensors are substitutable as means for determining glucose levels of a patient (Starkweather [0051]).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shusterman in view of Heilman et al. US Patent Publication Number 2003/0158593 (hereinafter Heilman) as applied to claim 3 and further in view of Kloecker US Patent Number 6,315,745.

Regarding claim 20, Shusterman as modified by Heilman disclose a jacket having a plurality of zones and an electroshock device (see rejection for claim 3 above). Shusterman as modified by Heilman teach user of therapeutic medical devices such as drug therapy device (medication dispensing unit, fig 2A, unit 212) and electroshock device (Heilman; abstract and [0002 and 0010]). However, Shusterman as modified by Heilman do not teach that jacket or garment has plurality of airbags selected from the group consisting of airbags that apply cardio-

pulmonary resuscitation, airbags that apply abdominal thrust and/or airbags that apply a sudden pressure to simulate the user to determine whether the user is conscious.

Kloecker, a reference in an analogous art, discloses a garment comprising inflatable air bags (column 9, line 52 – column 10, line 56). The inflatable bags further having pressure sensors 9 (column 10, lines 35-56). Since airbags disclosed by Kloecker are inflatable, they can be used to apply sudden pressure to the user therefore the structure of airbags disclosed by Kloecker is sufficient to reject the structure of airbags claimed i.e. *airbags selected from the group consisting of airbags that apply cardio-pulmonary resuscitation, airbags that apply abdominal thrust and/or airbags that apply a sudden pressure to simulate the user to determine whether the user is conscious.*

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the garment disclosed by Shusterman and Heilman in view of garment taught by Kloecker since doing so would provide a treating device for i.e. inflatable airbags in addition to the drug therapy and electroshock device taught by Shusterman and Heilman.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ATIA SYED whose telephone number is (571)270-7134. The examiner can normally be reached on Monday through Friday, 9:00-5:00 pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ATIA SYED/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769

March 25, 2010